JUN 2 4 2005

K051546

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Contact Person: Dr. Ting Choon Meng, M.D.

Position/Title: President/CEO

Date of Preparation: June 6, 2005

(2) **Trade Name:** MC3000/MC3100 Oscillometric Blood Pressure Monitor

Common/Classification Name: System, Measurement, Blood-pressure, Non-invasive

Product Code: 74 DXN, 21 CFR § 870.1130

Class: Class II

(3) **Predicate Device(s):**

K982481 UA-767PC Digital Blood Pressure Monitor, A & D Medical

Reason for Submission: New Device

(4) **Description of Device:**

The BPCalibrator™ MC3000/MC3100 is an oscillometric blood pressure monitor for measuring systolic pressure, diastolic pressure and pulse rate at home or in clinical settings.

A cuff is applied to the upper arm before measurement. When a measurement is initiated, the cuff is inflated to a pressure higher than the systolic pressure and then deflated. Pressure pulses measured from the cuff during deflation are used to calculate blood pressure and pulse rate using the oscillometric method.

(5) **Intended use:**

Blood pressure is measured in millimeters of mercury (mmHg) and is represented in this application by two values: systolic pressure and diastolic pressure. The systolic pressure represents the pressure in the blood vessels when the heart contracts (pumps), while the diastolic pressure is the pressure when the heart relaxes and blood fills the heart.

Blood pressure fluctuates throughout the day. Specific ranges are associated with normal, hyper- and hypotension. Blood pressure may be measured by persons in order to be better informed of their condition and to assist their doctor in assessing and specifying a treatment.

Indications for Use:

The BPCalibrator™ MC3000/MC3100 is an oscillometric blood pressure monitor for measuring systolic pressure, diastolic pressure and pulse rate. The device is intended for use at home or in doctor's office settings on patients who are eighteen (18) years and older and who do not have common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation. The arm circumference range shall be between 8.3 inches (21 cm) and 16.5 inches (42 cm).

The BPCalibrator™ MC3000 has a communication port that enables blood pressure and pulse rate readings to be transmitted to other electronic devices designed to communicate with it.

Blood pressure and pulse rate readings obtained using the device are intended for use by qualified healthcare personnel as an aid to diagnosis and treatment.

(6) **Technological Characteristics:**

The BPCalibrator™ MC3000/MC3100 oscillometric blood pressure monitors embody similar technological characteristics as the predicate device. An embedded microcontroller operates an air pump for cuff inflation and an electric valve to control cuff deflation. A pressure transducer measures the pressure signals from the cuff and the blood pressure is calculated by the oscillometric method. The devices are battery operated and utilize an LCD for display of the measurements. The MC3000 and predicate device are capable of serial communication via an RS-232 port. The MC3100 has a historical memory capable of calculating the previous 20 measurements.

(b) (1) **Non-Clinical Tests Submitted:**

The BPCalibrator™ MC3000/MC3100 devices were tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, shock and vibration, and environment (temperature and humidity). The devices passed the tests.

Accessory devices (NIBP cuffs) were evaluated for conformance with labeling and biocompatibility requirements. The cuffs met the requirements.

System level tests including measurement accuracy and stability, and inflation and deflation safety were performed to applicable standards for non invasive blood pressure devices. The requirements of the standards were met.

The BPCalibrator™ MC3000/MC3100 embedded software was verified to requirements and validated to meet intended use. Risk and failure mode analysis was performed and residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:**

The BPCalibrator™ MC3000/MC3100 was clinically tested in accordance with AAMI-SP10: 1992, Electronic or Automated Sphygmomanometers. The requirements of the standard were met.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, all of the testing demonstrates that the BPCalibrator™ MC3000/MC3100 oscillometric blood pressure monitors are as safe and effective as, and function in a manner equivalent to the predicate device, the UA-767PC Digital Blood Pressure Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2005

HealthSTATS International Pte. Ltd.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K051546
Trade Name: BPCalibrator MC3000/MC3100 Oscillometric Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: June 10, 2005
Received: June 13, 2005

Dear Mr. Mosenkis:

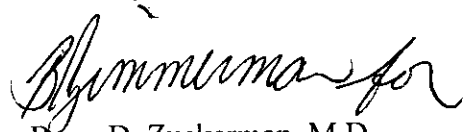
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051546

Indications for Use

510(k) Number (if known):

Device Name: HealthSTATS BPCalibrator MC3000/MC3100 Oscillometric Blood Pressure Monitor

Indications for use:

The BPCalibrator™ MC3000/MC3100 is an oscillometric blood pressure monitor for measuring systolic pressure, diastolic pressure and-pulse rate. The device is intended for use at home or in doctor's office settings on patients who are eighteen (18) years and older and who do not have common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation. The arm circumference range shall be between 8.3 inches (21 cm) and 16.5 inches (42 cm).

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Prescription Use _____ AND / OR Over-The-Counter Use ____X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051546